

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MONSANTO COMPANY,

Plaintiff,

vs.

BAYER BIOSCIENCE N.V.,

Defendant.

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Case No. 4:00CV01915 ERW

MEMORANDUM AND ORDER

This matter comes before the Court upon Defendant's Motion for Judgment as a Matter of Law [doc. #756]. On December 4, 2000, Monsanto Company [Monsanto] filed suit against Bayer Bioscience N.V. [Bayer] seeking a declaratory judgment that Monsanto's MON810 product, also known as YieldGuard, does not infringe on certain patents owned by Bayer. Monsanto also seeks a declaratory judgment alleging that Bayer's patent claims are invalid due to (1) lack of enablement; (2) obviousness; and (3) a prior invention. The Court will assume that the reader is familiar with the Court's May 10, 2005 Orders on Defendant's Motions for Summary Judgment [docs. #543, 544, and 545].

II. MOTION FOR JUDGMENT AS A MATTER OF LAW STANDARD

Pursuant to Federal Rule of Civil Procedure 50(a)(1):

[i]f during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

Fed. R. Civ. Pro. 50(a)(1). The inquiry on a motion made pursuant to Rule 50 ("Rule 50 motion") is the same as that for summary judgment. *Kinserlow v. CMI Corp.*, 217 F.3d 1021,

1025 (8th Cir. 2000). The issue is “[w]hether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Id.* A Rule 50 motion should be granted where the plaintiff fails to make a submissible case of the required elements of a cause of action. *See Charles Woods Television Corp. v. Capital Cities/ABC, Inc.*, 869 F.2d 1155, 1160-61 (8th Cir. 1989).

When deciding a Rule 50 motion, the court draws all reasonable inferences in favor of the non-moving party and may not make credibility determinations or weigh the evidence. *Kipp v. Missouri Hwy & Transp. Comm’n*, 280 F.3d 893, 896 (8th Cir. 2002); *Kinserlow*, 217 F.3d at 1025. A reasonable inference is one which may be drawn from the evidence without resort to speculation. *Kinserlow*, 217 F.3d at 1026. Accordingly, judgment as a matter of law should be granted if the record contains no proof beyond speculation to support the verdict. *Id.* A court should grant a Rule 50 motion “when all of the evidence points one way and is susceptible of no reasonable inference sustaining the position of the nonmoving party.” *Id.* (internal quotations omitted). Importantly, a court must assume that the jury resolved all conflicts of evidence in favor of the non-moving party. *Walsh v. Nat’l Computer Sys., Inc.*, 332 F.3d 1150, 1158 (8th Cir. 2003). Moreover, a court must take as true those facts which tended to be proved by the prevailing party. *Id.* In short, a court should deny a Rule 50 motion if “reasonable jurors could differ as to the conclusion that could be drawn from the evidence.” *Id.* (internal quotation omitted).

III. DISCUSSION

A. Enablement

35 U.S.C. Section 112 requires that

[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.] . . . The specification shall conclude with one or more claims particularly pointing out

and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. § 112 (2004). “The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003). “Because the [a] patent is presumed valid, clear and convincing evidence must support a conclusion of invalidity.” *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004). In its May 10, 2005 Memorandum and Order granting in part, and deny in part, Bayer’s Motion for Partial Summary Judgment Dismissing Monsanto’s Defenses Under 35 U.S.C. § 112, this Court noted

it is not necessary that a patent applicant test all the embodiments of his invention; what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify grant of the claims sought.

Amgen, Inc. v. Chugai Pharm. Co., LTD., 927 F.2d 1200, 1212 (Fed. Cir. 1991). The Court reasoned that

the claims of the ‘565 patent say nothing about plants or expression in plants. The Court agrees with Bayer that the patent requires only a gene comprised of a DNA fragment **encoding an insecticidal Bt2 toxin**. It is improper to look at the expression levels alone to determine whether the claims are enabled. However, it is proper to determine if the reason for inconsistent expression is that the DNA fragment is, in fact, **not** encoding the insecticidal Bt2 toxin.

In this Court’s November 1, 2005 Order granting in part, and deny in part, Bayer’s Motion to Enforce Order Regarding Enablement, the Court held

so long as Monsanto produces evidence in support of its contention that the DNA fails to encode the insecticidal Bt2 toxin in a significant number of nucleotide combinations, it may produce evidence relating to expression levels. Second, the Court invites Monsanto to read the language on page 11, ‘[t]he

Court agrees with Bayer that the patent requires only a gene comprised of a DNA fragment **encoding an insecticidal Bt2 toxin.** Monsanto will not be permitted to present evidence relating to expression levels that does not in some way relate back to the patented gene **failing to encode the insecticidal Bt2 toxin.**

At the time the '565 patent application was filed, those with ordinary skill in the art would have been able to make the full scope of the claims by referring to a codon chart and substituting codons. Monsanto continues to argue that because some of the claimed genes did not express in certain plants, Bayer's patent was not enabled. This Court disagrees. Monsanto attempts to infer that the failures related to expression levels were due to the DNA fragment not encoding an insecticidal Bt2 toxin. Even drawing all inferences in favor of Monsanto, this Court must presume that the '565 patent is valid. Monsanto has finished presenting its case-in-chief,¹ and has not presented clear and convincing evidence that a significant portion of the claimed nucleotide sequences fail to encode an insecticidal Bt2 toxin. Thus, Bayer's Motion for Judgment as a Matter of Law will be granted as to Monsanto's defense of enablement.

B. Obviousness

35 U.S.C. Section 103(a) mandates that:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

¹Plaintiff cannot rely on evidence that may be elicited in cross-examination to defeat a motion for judgment as a matter of law that is filed at the close of plaintiff's case-in-chief. "Normally, parties are expected to present all of their evidence in their case in chief." *Gathright v. St. Louis Teacher's Credit Union*, 97 F.3d 266, 268 (8th Cir. 1996) (quoting *Skogen v. Dow Chem. Co.*, 375 F.2d 692, 705 (8th Cir.1967)). Rule 50 permits courts to make judgments as a matter of law after a "party has been fully heard on an issue." Fed. R. Civ. Pro. 50(a)(1). If this Court were to adopt Plaintiff's reasoning, it would follow that a defendant would never be entitled to judgment as a matter of law at the close of a plaintiff's presentation of its case-in-chief. Certainly, Plaintiff cannot argue that this result is anticipated under Rule 50. Furthermore, Plaintiff has not presented any evidence or argument that the Court did not permit it to be "fully heard" on the issues related to Defendant's instant motion.

subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103. In order to show that an invention was obvious based on prior art references, the Court must consider (1) “the scope and content of the prior art;” (2) “differences between the prior art and the claims at issue;” and (3) “the level of ordinary skill in the pertinent art.” *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 139 (Fed. Cir. 1986). Further, “secondary considerations as commercial success, long felt but unsolved need, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Id.* In this case, secondary considerations are not at issue.

Bayer argues that it is entitled to judgment as a matter of law that its claims were not obvious. Obviousness is a conclusion of law based on underlying factual inquiries. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). As a preliminary matter, this Court notes that expert testimony is not necessary to prove obviousness. *See Nutrition 21 v. United States*, 930 F.2d 867, 871 n.2 (Fed. Cir. 1991) (“[a]n expert’s opinion on the ultimate legal conclusion [of obviousness] is neither required nor indeed ‘evidence’ at all”). Drawing all inferences in favor of Monsanto, this Court finds that Monsanto has presented sufficient evidence that a reasonable factfinder could find the claims of the ‘565 to be obvious by clear and convincing evidence.²

B. Prior Invention

35 U.S.C. Section 102(g)(2) indicates that an applicant will not receive a patent if:

²The Court notes that with the evidence presented thus far, drawing all inferences in favor of Monsanto, a reasonable factfinder could find that Bayer’s conception of its invention was not until its filing date in January 1986. The April 18, 1985 date admitted by Bayer does not restrict Monsanto from arguing that conception did not occur until the filing date. Thus, Bayer’s argument that much of Monsanto’s evidence does not relate to prior art fails for this reason alone.

before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g)(2). In this Court's May 10, 2005 Order denying Defendant's Motion for Partial Summary Judgment Dismissing Monsanto's Defenses Under 35 U.S.C. Section 102, this Court held that:

Monsanto must show by clear and convincing evidence that its scientists had conception of the gene prior to Bayer filing the '565 patent application in order to be considered the prior inventor of the Bt2 chimeric gene. *See Mycogen Plant Science v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001).

This Court went on to explain when conception occurs, concluding that one has conception "when 'one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it.' *In re Wallach*, 378 F.3d 1330, 1335 (Fed. Cir. 2004)." The Court explained that although in prior cases courts have consistently held that an inventor does not have conception until he knows the nucleotide sequence of a DNA fragment, this case presents circumstances creating a genuine issue of material fact as to "whether Monsanto had knowledge of the chemical structure of the Bt gene fragment to such an extent that the fragment could adequately be distinguished from other chemical compounds" because of Monsanto's much more extensive knowledge of the DNA fragment at issue.

Bayer claims that Monsanto has presented no evidence that it had conception prior to Bayer's conception on April 24, 1985. Monsanto has presented sufficient evidence it had conception of the MON810 gene encoding an insecticidal toxin prior to Bayer's alleged

conception date.³ Furthermore, the Court finds that there has been additional evidence that would enable a reasonable factfinder to find that Monsanto's reduction to practice occurred prior to Bayer filing its patent application.⁴ Thus, Bayer's Motion for Judgment as a Matter of Law will be denied as it relates to Monsanto's prior inventorship defense.

Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion for Judgment as a Matter of Law [doc. #756] is **GRANTED in part** and **DENIED in part**. The Motion will be granted as it relates to Monsanto's enablement defense. The Motion will be denied as it relates to Monsanto's obviousness and prior inventorship defense.

Dated this 15th day of November, 2005.



E. RICHARD WEBBER

UNITED STATES DISTRICT JUDGE

³The Court further notes that Bayer's conception could be found by a reasonable factfinder to have been as late as January 1986. *See supra* n. 2.

⁴The Court finds Bayer's argument that "[t]he evidence of record shows that Monsanto did not reduce its purportedly prior invention to practice before this January 22, 1986 date because Monsanto did not demonstrate the intended purpose of that invention, *i.e.*, did not observe toxicity in plants, before this date" to be very troubling. The Court will not permit Bayer to argue in support of enablement that toxicity expression in plants is not necessary for enablement of its claims, but is necessary for Monsanto's reduction to practice. Monsanto need only show that its gene **encoded an insecticidal Bt2 toxin**, not that the plants expressed that toxin.